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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,184	02/28/2005	Izumi Sugo	14875-132US1	5347

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,184	SUGO ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-31* is/are pending in the application.

4a) Of the above claim(s) *26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-25 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/21/05* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/2/05,9/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 11/21/05 is acknowledged.
Claims 1-12 have been canceled.
Claims 13-31 have been added.
Claims 13-31 are pending.

2. Applicant's election without traverse of Group I, drawn to claims 13-25 and 28-31 (in lieu of claims 1-10), a method of generating a nucleic acid encoding a stabilized protein, in the reply filed on 11/21/05 is acknowledged.

Claims 26-27 are withdrawn from further consideration by the examiner, 37 C.F.R.§ 1.142(b) as being drawn to a nonelected invention.

Claim 13-25 and 28-31 is under consideration in the instant application.

3. Applicants' claim for foreign priority under 35 U.S.C. 119(a)-(d) is acknowledged.

4. Applicants' IDS filed on 3/2/05 and 9/16/05 have been considered.
However, the references AC and AD were not considered as Applicants failed to provide the foreign patent documents.

5. The amendment filed 11/21/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: p. 19 of substitute specification, line 4, mouse to mammal, line 14, non-mammalian to human, mammal. Applicant is required to cancel the new matter in the reply to this Office Action.

6. The replaced Fig. 2B filed on 11/21/05 is not consistent with the substituted specification in recitation of N54.

7. Applicants' representative, Ken Seidenman calling on behalf of Janis Fraser, further pointed out the additional support for new claims 17 and 25 on p. 15 lines 2-5, p. 16, lines 17-20 of the substitute specification. Applicant is invited to submit a written communication for completion of the record.

8. The following is a quotation of the second paragraph of 35 U.S.C.112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 13-25 and 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) The terms/phrase " first", "second" and "first region" recited in claim 13 are relative terms which render the claim indefinite. The "first" amino acid residue does not seem to be the 1st amino acid as in Gln in SEQ ID NO:25 for example but rather any amino acid susceptible for deamidation.
(B) The term "stabilized" in claims 13 and 18 are not defined.
(C) The phrase "susceptible to loss of " recited in claims 13 and 18 are relative which renders the claim indefinite.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 13-25 and 28-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection for the following reasons:

The specification as filed does not provide a written description or set forth the metes and bounds of the method steps (a-f) other than generically cited expression vectors, p. 11, lines 29-31. The specification does not provide guidance nor direction for the above-mentioned steps as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicants provide the written support for newly added claims in originally filed claims 1-12, however, the original claims are drawn to a method for stabilizing protein while new claims are drawn to method for generating a nucleic acid encoding a stabilized protein.

Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, Applicant is invited to provide clearly point out the written support for the instant limitations.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 13,14 16-19, 22-25 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.Pat. No. 6,172,213 B1 (IDS reference, AB).

The '213 patent teaches a nucleic acid encoding IgE antibody (i.e. biologically active polypeptide) by a method including, identifying aspartyl residues (or asparaginyl residues in deamidation) which are prone to isomerization, substituting of alternative residues, and screening of resultant mutants (col. 3, lines 13-23, claims 1-7, col. 15, lines 8-33, col. 16, lines 11-25, col. 23-24).

The '213 patent further teaches expression of the nucleic acid in host cells, harvesting (col. 46, under vectors and host cells) and humanized MaE11 antibody of CDR2 residues.

The '213 patent includes the deamidation in the scope (col. 46, lines 2-8) and isomerization of asparaginyl residues are included to improvement of polypeptide (col. 16, lines 20-25). Thus, the reference teachings encompass asparaginyl residues as amino acid residues that are prone to isomerization (i.e.deamidation col. 46, lines 3-8).

Due to lack of definition of "stabilized" or "susceptible to loss of", the claims interpreted to improve affinity (col. 3, lines 2-8, col. 1, lines 12-15).

As seen in amino acid residues 141-142 of SEQ ID NOs:13, 14 and 393-394 of SEQ ID NO:16 of the '213 patent where two consecutive asparaginyl residues appeared, the alteration of amino acid next to the amino acid being deamidated reads on the second asparaginyl residue. Thus, the reference teachings anticipate the claimed invention.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 13-25 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.Pat. No. 6,172,213 B1 (IDS reference, AB) in view of Tyler-Cross et al. (J. Biol. Chem, 1991,256 (33): 22549-22556, IDS reference, AO) as is evidenced by Manning et al. (Pharmaceutical Research, vol. 6, 903-918, 1989).

The '213 patent has been discussed, supra.

The '213 patent does not teach the adjacent amino acid residue to an amino acid being deamidated is glycine.

However, Tyler-Cross et al. teach the effect of the side chain adjacent to the amino acid being deamidated and disclose any modification to glycine in "-Asn-Gly-" structure decreases the rate of deamidation by as much as 70 fold (abstract, p. 22549, col. 2, 2nd paragraph, p. 22550-51, results).

As is evidenced in Manning et al., the deamidation plays important role in stability of protein in pharmaceuticals and modification to stabilize proteins includes use of site directed mutagenesis (abstract, introduction and under deamidation).

Therefore, one of the ordinary skill in the art would have been motivated to combine the modification of glycine residue as taught by Tyler-Cross et al. and Manning et al. in the nucleic acid encoding a polypeptide or antibody as taught by the '213 patent to improve stability of protein by reducing the rate of deamidation.

From the teachings of references, one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

16. No claims are allowable.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 8, 2006

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